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IN THE UNITED STATES PATENT & TRADEMARK OFFICE AUG 25 2005

In re Application of:) Docket No. DN2001-192D01
Michael Lester Kerns, et al) Art Unit: 3727
For: RUBBER FOR BABY BOTTLE) Examiner:
NIPPLES, PACIFIERS & SYRINGE)
PLUNGERS) I hereby certify that this correspondence is being
Serial No.: 10/808,856) facsimile transmitted to the United States Patent and
Filed: March 25, 2004) Trademark Office to facsimile number (571) 273-8300 on
August 25, 2005.

Mary A. Nicloff

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE IN COMPLIANCE WITH 37 C.F.R. §1.98

As a means of complying with the duty of disclosure set forth in 37 C.F.R. §1.56, the Applicants are calling the following to the attention of the Patent Office and request that they be considered by the Examiner:

United States Patent 6,001,478
United States Patent 6,221,447
United States Patent 3,297,667
United States Patent 3,676,411
United States Patent 3,794,604
United States Patent 4,030,498
United States Patent 4,180,069
United States Patent 4,242,232
United States Patent 4,258,714
United States Patent 4,260,707
United States Patent 4,405,317
United States Patent 4,412,836
United States Patent 4,444,903
United States Patent 4,663,405

United States Patent 4,699,960
United States Patent 4,676,386
United States Patent 4,701,165
United States Patent 5,114,415
United States Patent 5,653,732
United States Patent 5,699,921
United States Patent 5,779,668
United States Patent 5,785,682
United States Patent 5,823,998
United States Patent 5,876,372
United States Patent 6,196,998
United States Patent 6,217,550
United States Patent 6,241,112
United States Patent 6,253,935

However, the above-listed references may not be prior art under 35 U.S.C. §102 and this document should not be construed as an admission that any of the above-listed references are prior art within the meaning of 35 U.S.C. §102.

United States Patent 6,001,478 and United States Patent 6,221,447 may be relevant to the prosecution of the subject patent application because they were cited by the Examiner during the prosecution of United States Patent 6,871,751 of which this application is a divisional.

United States Patent 3,297,667, United States Patent 3,676,411 and United States Patent 3,794,604 may be relevant to the prosecution of the subject patent application because they disclose variations and improvements to polymerization catalyst compositions and processes for polymerizing diolefins therewith.

United States Patent 4,030,498 may be relevant to the prosecution of the subject patent application because it discloses a syringe comprised of a barrel defining a bore and having a discharge portion, and a plunger extending into said bore and movable therewithin, in combination with an inner sealing means carried by said plunger and movable axially within said bore in an area proximate to said discharge portion for substantially preventing leakage of medicament or other biologic fluid contained in the space forward of said inner sealing means adjacent said discharge portion; outer sealing means carried by said plunger, said outer sealing means being spaced axially from said inner sealing means and movable axially within said bore in an area behind the travel area of said inner sealing means; said

plunger having an axial length within the bore of more than one-half of the functional length of the bore void of sealing rings; and means for preventing said outer sealing means from moving in the area in which said inner sealing means travels.

United States Patent 4,180,069 may be relevant to the prosecution of the subject patent application because it discloses a piston used for a syringe.

United States Patent 4,242,232, United States Patent 4,260,707, United States Patent 4,699,960 and United States Patent 4,444,903 may be relevant to the prosecution of the subject patent application because they disclose high *cis*-polybutadiene for use in tire applications.

United States Patent 4,258,714 may be relevant to the prosecution of the subject patent application because it discloses an ear syringe having a built-in pressure regulator valve to control the discharge velocity of fluid issuing from the nozzle of the syringe, regardless of the amount of pressure applied on the bulb of the syringe, to prevent pain in the ear of a user, or possible damage to the ear as a result of squeezing the bulb too hard, or applying a sudden excessive pressure to the bulb.

United States Patent 4,405,317 may be relevant to the prosecution of the subject patent application because it discloses a syringe assembly comprising an outer barrel for a powder medicament, an inner barrel telescopically mounted in the outer barrel for diluent, seal means isolating the powder and diluent compartments comprising a plug member made of a resilient material sealingly engaging in the discharge opening of the inner barrel, plunger means mounted on the discharge end of the inner barrel including a hollow plug chamber closed at one end remote from the discharge end of the inner barrel by a wall having a plurality of discharge openings therein, said plug member including a pintle projecting from one axial end face thereof of said plug member of a diameter less than the body portion of said plug member and greater than the discharge openings in said plunger end wall, said plug member adapted upon pressure buildup in the inner barrel to be displaced axially outwardly into said plug chamber to permit flow of diluent from the inner barrel to the powder compartment.

United States Patent 4,412,836 may be relevant to the prosecution of the subject patent application because it discloses a plunger for a syringe made of a resilient material comprising a generally cylindrical body portion, a plurality of radial axially spaced ribs on its outer peripheral, a rupturable diaphragm spaced inwardly from opposite axial ends of the body portion, said diaphragm having a localized weakened area to minimize particle

formations when the diaphragm ruptures, and also providing a more accurate control of force required to rupture the diaphragm consisting of a crescent-shaped membrane portion of thinner cross section than the remainder defined by the crescent and the circular trace of the diaphragm.

United States Patent 4,663,405 may be relevant to the prosecution of the subject patent application because it discloses vinyl halides which can be utilized as molecular weight regulators.

United States Patent 4,676,386 may be relevant to the prosecution of the subject patent application because it discloses baby bottle nipples and pacifiers.

United States Patent 4,701,165 may be relevant to the prosecution of the subject patent application because it discloses a push rod for a syringe, said push rod having a hole in its end, a first section of the hole being threaded near the entrance of the hole, a second section of the hole which is remote from the entrance having an internal diameter which is larger than the diameter of the first threaded section in order to form a clearance room at the inner end of said hole, a plunger having a stud with an interrupted thread, the outer end of said stud having a thread which meshes and mates with the thread in said first section and the inner end of said stud having a smooth perimeter with a diameter which is less than the diameter of said first section of said hole, whereby said smooth inner end of said stud moves freely within the threaded section near the entrance of said hole.

United States Patent 5,114,415 may be relevant to the prosecution of the subject patent application because it discloses an apparatus for removing fluid secretions from a patient's upper airway which includes a power driven suction generator connected to one end of a flexible tube and a nozzle removably connected to the other end of the tube.

United States Patent 5,653,732 may be relevant to the prosecution of the subject patent application because it discloses baby bottle nipples.

United States Patent 5,699,921 may be relevant to the prosecution of the subject patent application because it suggests the use of a check-valve which can be formed by elastic lips in a system for use in delivering air into the interior of a baby bottle while the baby is feeding. It further discloses two opposing lips which open under a certain inner vacuum of the bottle to let air in the bottle.

United States Patent 5,779,668 may be relevant to the prosecution of the subject patent application because it discloses a syringe system comprising a primary syringe barrel having a delivery end defining a delivery passage and an opposite end having an edge and a venting portion with an inner surface and a larger transverse cross section; a removable

closure sealing the delivery passage of the primary syringe barrel to define a chamber for containing a medical solution; a plurality of longitudinal channels on the inner surface of the venting portion of the open end of said primary syringe barrel; a plurality of rib portions in the venting portion between said channels, said opposite end of said primary syringe barrel has a smooth portion along the inner surface between said edge and said rib portions; and a reciprocable stopper for slidably sealing said primary barrel wherein the reciprocable stopper has a first position abutting the channels of the inner surface of the venting portion to allow the medical solution to be lyophilized, and is then axially movable in the direction of the delivery passage to a second position to sealingly enclose the lyophilized drug within the sealed delivery end of the primary syringe barrel.

United States Patent 5,785,682 may be relevant to the prosecution of the subject patent application because it discloses a drug delivery system, comprising a first pre-filled syringe assembly comprising a first syringe barrel having an interior surface, an open end, and an opposite delivery end which defines a drug delivery passage; a reciprocable stopper slidably disposed within said first syringe barrel in sealing engagement therewith for defining an internal mixing chamber within said first syringe barrel in communication with said delivery passage; and a sterility maintenance sleeve extending from said reciprocable stopper toward said open end of said first syringe barrel, said sterility maintenance sleeve maintaining the sterility of the interior surface of said first syringe barrel; a second pre-filled syringe assembly comprising a second syringe barrel having a fluid discharge passage at one end thereof, said second syringe barrel being sized to be disposed within the sterility maintenance sleeve of said first syringe assembly a movable piston plunger positionable within said second syringe barrel to define a fluid chamber therewith in communication with said fluid discharge passage; and a liquid in the fluid chamber of said second syringe barrel; and said system further including fluid transfer connector means for providing fluid communication from the fluid chamber of said second syringe assembly to said internal mixing chamber of said first syringe assembly when said second syringe assembly is disposed within said sterility maintenance sleeve so that the liquid within said fluid chamber can be caused to flow through said fluid transfer connector means into said internal mixing chamber of said first syringe assembly by movement of said piston plunger toward said fluid discharge passage of said second syringe assembly and thereafter caused to flow from said mixing chamber of said first syringe assembly through said drug delivery passage by movement of said second syringe assembly together with said reciprocable stopper and said sterility maintenance sleeve toward the drug delivery passage of said first syringe assembly, said fluid transfer

connector means includes means for regulating the flow of fluid through said reciprocable stopper, said reciprocable stopper has an outer side facing toward said open end of said first syringe barrel and an inner side facing toward said drug delivery passage, said means for regulating the flow of fluid through said reciprocable stopper comprises said reciprocable stopper having a resilient body with a longitudinal slit through the resilient body defining two normally closed resilient lips, and the resilient body of said reciprocable stopper is substantially hollow and includes an enlarged cavity and a smaller entrance passage; and said sterility maintenance sleeve further includes: an enlarged head for being received in said enlarged cavity un said enlarged cavity of said resilient body, a smaller neck for being received in said smaller entrance passage of said resilient body, and a radially extending support flange adjacent said smaller neck for axially supporting said reciprocable stopper outer side.

United States Patent 5,823,998 may be relevant to the prosecution of the subject patent application because it discloses an injection apparatus, comprising an ampule having a piston for sealing an agent in a syringe, comprising: piston rod means for pressing the piston of the ampule in an axial direction; an ampule holding part having an ampule insertion outer opening, having an original circumference, which opening is expanded circumferentially when the ampule is inserted into the opening and having an ampule insertion space for inserting the ampule thereinto, wherein the outer opening is restored to its original circumference after the ampule is inserted into the ampule insertion space, so that the ampule is held by the ampule holding part temporarily; and ampule gripping means for gripping the ampule and preventing axial movement thereof wherein a concave part is formed on a peripheral surface of the piston rod, wherein the concave part comprises a bottom surface generally parallel with an inner peripheral surface of the guide sleeve, a front step surface being provided on a front side of the bottom surface and extending from the bottom surface outwardly in a radial direction of the piston rod, and a rear step surface being provided on a rear side of the bottom surface and extending from the bottom surface outwardly in the radial direction of the piston rod, and wherein the piston rod means further comprises spring means for automatically returning the screw rod and the piston rod to the initial position when a force for pushing in the screw rod and the piston rod is released, and a stopper member which is positioned in the concave of the piston rod, slides in contact with the bottom surface of the piston rod and the inner peripheral surface of the guide sleeve with a predetermined frictional force, moves together with the piston rod with the stopper member in contact with the rear step surface of the piston rod when the piston rod is pushed in, and stops the movement of the

piston rod with the stopper member in contact with the front step surface of the piston rod when the piston rod is returned by the spring means, wherein a frictional force between the stopper member and the bottom surface of the piston rod is smaller than an automatic return force of the spring means; and a frictional force between the stopper member and the inner peripheral surface of the guide sleeve is greater than the automatic return force of the spring.

United States Patent 5,876,372 may be relevant to the prosecution of the subject patent application because it discloses a syringe mixing and delivery system comprising a first barrel having an open end and an opposite delivery end defining a delivery passage; a reciprocable stopper sealingly disposed in said first barrel to define a first chamber between said delivery passage and said reciprocable stopper for containing a first constituent in said first chamber; a second barrel that is sized to be disposed in said first barrel and that has an open end and an opposite discharge end defining a discharge passage; a slidable plunger sealingly disposed within said second barrel to define a second chamber between said discharge passage and said slidable plunger for containing a liquid second constituent in said second chamber; and fluid transfer connector means for operatively connecting said second barrel with said reciprocable stopper to permit flow of said liquid second constituent through said stopper from said second chamber to said first chamber to mix with said first constituent when said second barrel discharge end and plunger are moved closer together whereby subsequent movement of said second barrel and reciprocable stopper together toward said delivery passage of said first barrel expresses the mixed constituents out of said first chamber through said delivery passage.

United States Patent 6,196,998 may be relevant to the prosecution of the subject patent application because it discloses a syringe with a syringe barrel having a substance receiving chamber and a distally projecting tip with a fluid passage extending therethrough and a tip cap assembly attached to the projecting tip, said tip cap assembly comprising a collar concentrically surrounding the tip, the collar including an array of internal threads for threadingly engaging a needle hub; a resilient inner cap having opposed proximal and distal ends, said proximal end defining a tip engaging portion for sealingly engaging the tip to seal a substance contained in the chamber of said syringe barrel; a rigid outer cap securely engaged around at least a portion of said inner cap, said outer cap having a sleeve engageable with the collar such that said outer cap securely and releasably retains said collar therein and said inner cap in sealing engaged with the tip; and tamper indicator means provided on said sleeve of said outer cap for indicating separation of said outer cap from said collar and said tamper indicator means including a plurality of frangible portions separating said outer cap

into a proximal portion and a distal portion, with the proximal portion surrounding said collar.

United States Patent 6,217,550 may be relevant to the prosecution of the subject patent application because it discloses a syringe comprising: a barrel having a fluid chamber, a proximal end, a distal end and an elongated tip extending from said distal end having a passageway therethrough in fluid communication with said chamber; and a plunger including an elongated plunger rod having a longitudinal axis, a proximal portion and a distal portion connected by a breakable connection, one of said proximal portion and said distal portion including an axial projection having a plurality of transverse protuberances projecting therefrom, said protuberances being connected to the other of said proximal portion and said distal portion, said breakable connection being on said protuberances, said distal portion including a stopper slidably positioned in fluid-tight engagement with an inside surface of said chamber for drawing fluid into and out of said chamber by movement of said plunger relative to said barrel, said breakable connection being strong enough to hold said proximal portion and said distal portion together during normal use of said syringe and breakable upon application of an additional force applied to said proximal portion along said longitudinal axis.

United States Patent 6,241,112 may be relevant to the prosecution of the subject patent application because it discloses a stopper for sealing infusion bottles containing pharmaceutical liquids, which stopper has a collar, which projects into the opening in the neck of the container and has a diameter greater than the neck opening; an edge, which rests on the neck of the container; and a puncture area, enclosed by the edge and the collar, the stopper being held on the neck of the container by a protective cap of metal or plastic, characterized in that the top surface of the puncture area is lower than the top surface of the edge, and in that the bottom surface of the stopper inside the collar as well as the top surface of the puncture area are relatively flat, and in that a transverse plane formed by end surface of container neck passes through approximately the center of the vertical thickness of the puncture area, and wherein the length of said collar is generally the same as the cross sectional thickness of the puncture area, the puncture area having a predetermined elasticity and flexibility with respect to the edge and the collar whereby after the stopper has been inserted into the neck of container, the puncture area bulges slightly outward and remains in that position until the puncture needle of an infusion kit has been inserted into the stopper, and in that the puncture area bulges down into neck of the container when being pierced by the puncture needle and remains in this position as long as the puncture needle is inserted into

the stopper.

United States Patent 6,253,935 may be relevant to the prosecution of the subject patent application because it discloses nipples for baby bottles.

Form PTO-1449 is enclosed herewith.

Respectfully submitted,

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Sheet 1 of 3

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY DOCKET NO. DN2001-192D01	SERIAL NO. 10/808,856
APPLICANT(S) Michael Lester Kerns, et al		
FILING DATE March 25, 2004	GROUP 3727	

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub-class	Filing Date if Appropriate
	6,001,478	12/14/99	Apecetche et al	428	407	
	6,221,447	04/24/01	Munn et al	428	34.9	
	3,297,667	01/1967	Van Dohlen et al	260	82.1	
	3,676,411	07/1972	Throckmorton et al	260	82.1	
	3,794,604	02/1974	Throckmorton et al	252	431 C	
	4,030,498	06/1977	Tompkins	128	218 P	
	4,180,069	12/1979	Walters	128	218 P	
	4,242,232	12/1980	Sylvester et al	252	429 C	
	4,258,714	03/1981	Leopoldi et al	128	232	
	4,260,707	04/1981	Sylvester et al	526	114	
	4,401,317	09/1983	Case	604	90	
	4,412,836	11/1983	Brignola	604	87	
	4,444,903	04/1984	Carbonaro et al	502	102	

FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Country	Class	Sub-Class	Translation yes no

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner Initial		
EXAMINER	DATE CONSIDERED:	

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 2 of 3

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U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub-class	Filing Date if Appropriate
	4,663,405	05/1987	Throckmorton	526	144	
	4,699,960	10/1987	Gordini et al	526	81	
	4,676,386	06/1987	Philaphongphanich	215	11 R	
	4,701,165	10/1987	DeHaire	604	228	
	5,114,415	05/1992	Shedlock	604	319	
	5,653,732	08/1997	Sheehy	606	236	
	5,699,921	12/1997	Rodrigues	215	11.5	
	5,779,668	07/1998	Grabenkort	604	89	
	5,783,682	07/1998	Grabenkort	604	82	
	5,823,998	10/1998	Yamagata	604	131	
	5,876,372	3/1999	Grabenkort et al	604	89	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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Sheet 3 of 3

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